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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* WUMIN LI and HSIEN-JUE CHU

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Appeal 2011-000514
Application 10/796,925
Technology Center 1600

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Before TONI R. SCHEINER, MELANIE L. McCOLLUM, and STEPHEN WALSH, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for reducing bacterial shedding. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 22-24 are pending and on appeal (App. Br. 3). Claim 22 is representative and reads as follows:

22. A method for reducing shedding of *E. coli* O157:H7 in an animal which comprises administering by parenteral injection to the animal an effective amount of a vaccine composition, wherein the vaccine composition

comprises inactivated or killed whole *E. coli* O157:H7, an adjuvant and aluminum hydroxide, and optionally a pharmaceutically acceptable carrier;

wherein said adjuvant is an oil emulsion comprising:

(a) 1% to 3% vol/vol of polyoxyethylene-polyoxypropylene block copolymer;
(b) 2% to 6% vol/vol of squalane;
(c) 0.1 % to 0.5% vol/vol of polyoxyethylene sorbitan monooleate; and
(d) buffered salt solution.

Claims 22 and 24 stand rejected under 35 U.S.C. § 103(a) as obvious over Johnson[1] in view of Saito[2] and Baylor[3] (Ans. 3).

Claims 22-24 stand rejected under 35 U.S.C. § 103(a) as obvious over Johnson in view of Saito, Baylor, and Elder[4] (Ans. 5-6).

I

In rejecting claims 22 and 24, the Examiner relies on Johnson for disclosing "a study to determine the effect of vaccinating dairy claves [sic, calves] with an inactivated *Escherichia coli* O157:H7 bacterin on the shedding of Escherichia *coli* O157:H7" (Ans. 3). The Examiner finds that Johnson discloses "that six newly weaned calves were vaccinated intramuscularly with an inactivated *E. coli* O157:H7 bacterin" and "that the

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[1] Johnson et al., *Effect of vaccination of dairy calves with an inactivated Escherichia coli O157:H7 bacterin on shedding of E. coli O157:H7*, Abstract 40aP (1999).
[2] Saito et al., US 2005/0158330 A1, Jul. 21, 2005.
[3] Baylor et al., *Aluminum salts in vaccines – US perspective*, 20 VACCINE S18-S23 (2002).
[4] Elder et al., *Intervention to reduce fecal shedding of enterohemorrhagic Escherichia coli O157:H7 in naturally infected cattle using neomycin sulfate*, 80 J. Animal Sci. 151 (2002).

shedding of the organism by most calves in each group fell to 50 CFU/g of feces within 2-3 weeks of challenge" (*id.* at 3-4).

The Examiner relies on Saito for disclosing "oil adjuvant vaccines which include sorbitan fatty acid ester (e.g., sorbitan monooleate, etc.), non-ionic surfactants, having a polyoxyethylene chain in a molecule, such as polyoxyethylene sorbitan fatty acid ester polysorbate (e.g., polyoxyethylene(20)sorbitan monooleate etc.), polyoxyethylene polyoxypropylene glycol and the like as well as squalene" (*id.* at 9). The Examiner finds that Saito discloses "that the aqueous component of the vaccine is phosphate buffered physiological saline and the like"; "that the vaccine comprise[s] antigens of inactivated cells from Gram negative bacteria such as *Escherichia coli*"; "that suitable administration routes include subcutaneous, intramuscular and intraperitoneal injections"; and "that the vaccine comprises an aluminum hydroxide as an adjuvant" (*id.*).

The Examiner relies on Baylor for disclosing "that aluminum hydroxide has been commonly used as an adjuvant in many vaccines for decades and ha[s] been proven safe" (*id.* at 5).

The Examiner concludes that it would have been obvious "to modify the invention of Johnson et al. with the teachings of Saito et al. because Saito et al. disclose a vaccine which comprises inactivated cells of *E. coli* antigen coupled with an adjuvant comprising the components of SP oil" (*id.* at 4). The Examiner also concludes that it would have been obvious "to modify the invention of Johnson et al. with the teachings of Saito et al. to use inactivated whole *E. coli* O157:H7 because it is highly potent and can cause severe infections" (*id.*). In addition, the Examiner concludes that it

"would have been obvious to use the components together along with aluminum hydroxide because aluminum hydroxide is a known adjuvant that is well known in the art to stimulate an immune response[, a]s evidenced by Baylor" (*id.* at 4-5).

*Principles of Law*

An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Instead, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* In addition, an "obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art." *Amgen Inc. v. F. Hoffman-LA Roche Ltd*, 580 F.3d 1340, 1362 (Fed. Cir. 2009).

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citation omitted). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

*Analysis*

The Examiner concludes:

> It would have been expected, barring evidence to the contrary, that the composition would be effective in reducing shedding of

> *E. coli* O157:H7 because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

(Ans. 5.)

Appellants argue, however, that "the Examiner misinterprets Johnson and fails to properly ascertain the differences between Johnson and the claimed invention" (Amended App. Br. 5 (emphasis omitted)). In particular, Appellants argue:

> Johnson reports that a vaccine comprising *E. coli* O157:H7 did not have a significant effect on shedding of bacteria. Thus Johnson provides explicit "evidence to the contrary" that, at the time the invention was made, one of ordinary skill in the art would have a reasonable expectation that the claimed composition would be effective in reducing shedding of *E. coli* O157:H7.

(*Id.* at 10.)

We agree with Appellants that the Examiner has misinterpreted Johnson. In particular, Johnson discloses that "there was little difference between vaccinated and control calves in the levels and duration of shedding of *E. coli* O157:H7 after challenge" (Johnson, Abstract). As relied upon by the Examiner (Ans. 3-4), Johnson also discloses that "[s]hedding of the organism by most calves *in each group* [that is, vaccinated and unvaccinated control] fell to <50 CFU/g of feces within 2-3 weeks of challenge" (Johnson, Abstract (emphasis added)). However, this teaching does not indicate that the vaccine reduces shedding. On the contrary, Johnson states that these "findings indicate that infection of naturally-reared weaned dairy

calves by *E. coli* O157:H7 is frequently transient, . . . and is unlikely to be controlled by immune responses induced by parenterally administered inactivated bacterins" (*id.*).

In response to Appellants' arguments, the Examiner continues to argue that Johnson teaches a reduction in shedding, albeit only a small reduction (Ans. 11-12). However, it is by no means clear that Johnson even teaches this. Thus we agree with Appellants that the Examiner's response is inadequate.

Appellants also argue that "Saito never states or suggests that aluminum hydroxide could or should be used in such W/O/W adjuvants" (Amended App. Br. 6). In addition, Appellants argue that "the Examiner has failed to correctly identify any reason why one of ordinary skill in the art would combine elements of the prior art to arrive at the claimed invention" (*id.* at 11).

In response to these arguments, the Examiner states that, "[c]oupling the suggestion of Saito [of both oil adjuvant and aluminum hydroxide] with the evidentiary teachings of Baylor, . . . one of skill in the art has proper motivation, teaching and suggestion to combine an oil adjuvant with aluminum hydroxide" (Ans. 13). However, as pointed out by Appellants, Saito "mentions aluminum hydroxide in the context of being used . . . in comparative control vaccine compositions" (Amended App. Br. 6), not in combination with the oil adjuvant (Saito, e.g., ¶ [0101]). Thus, we agree with Appellants that the Examiner's conclusory statement that it would have been obvious to combine them, without articulating a reason therefor, is inadequate.

*Conclusion*

The Examiner has not set forth a prima facie case that Johnson, Saito, and Baylor suggest the method of claim 22. We are therefore compelled to reverse the rejection over these references.

II

In the second rejection, the Examiner relies on Johnson, Saito, and Baylor as discussed above (Ans. 5-6). The Examiner additionally relies on Elder for disclosing "an intervention to reduce fecal shedding of *E. coli* O157:H7 in naturally infected cattle when administered neomycin" (*id.* at 7), neomycin administration being recited in dependent claim 23. However, the Examiner does not rectify the deficiencies of the first rejection. We are therefore compelled to reverse this rejection as well.

REVERSED

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